

REMARKS/ARGUMENTS

Applicants submit the aforementioned amendments and following remarks in response to the Office Action mailed November 12, 2008.

Claims 15, 16 and 19-23 are pending. Claim 15 is amended. Support of the amendment may be found throughout the specification as originally filed, for examples, page 7. No new matter is added.

Reconsideration is respectfully requested in view of the above amendments and the following remarks.

The Rejections under 35 U.S.C. § 103(a)

Claims 15, 16 and 19-23 are rejected under 35 U.S.C. § 103(a) as alleged being unpatentable over JP 08231417 or Maitani in view of Collins, further in view of JP 61097229. Specifically, the Office states (1) JP '147 and Maitani disclose liposomes contain EPO, (2) Collin discloses the attachment of EPO to the surface of liposomes stabilizes EPO, and (3) JP '229 discloses glycine is a stabilizer for EPO.

Applicants respectfully submit that none of the cited documents, alone or in combination, disclose or suggest the claimed composition. The claimed liposomal-based composition is based on the unexpected discovery that the liposomal EPO compositions prepared under the mild conditions described in the present application exhibit improved stability, even though *EPO is not substantially incorporated within the liposomes and instead essentially contained in the aqueous buffer solution of the composition*. See page 4.

JP '417 discloses a liposomal dispersion wherein EPO is contained *within* the interior of the liposome. Maitani discloses a liposomal dispersion wherein a high percentage of EPO is encapsulated *within* the liposomes. Neither JP '417 nor Maitani disclose EPO being dispersed within the aqueous phase solution.

As stated by the Office, Collins discloses a formulation wherein EPO is *attached* to the outer surface of the liposomes. Collins is silent in EPO being dispersed within the aqueous phase solution. Accordingly, Collins does not cure the deficiency of JP '417 and Maitani.

JP '229 discloses glycine as a stabilizer for EPO. JP '229 is silent in EPO being dispersed within the aqueous phase solution. Accordingly, JP '229 does not cure the deficiency of JP '417 and Maitani.

As set forth in MPEP § 2143, three basic criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the cited art reference or references when combined must teach or suggest all the claim limitations. None of the above documents expressly or implicitly suggest that EPO being dispersed within the aqueous phase and not within the lipidic phase as the claimed composition.

Therefore, the forgoing criteria for a *prima facie* case of obviousness have not been met. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) are respectfully requested.

The Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 15, 16 and 19-23 are rejected under 35 U.S.C. § 112, second paragraph, as alleged being indefinite, specifically, the form of glycine.

In response, claim 15 is amended to specify glycine is dispersed within the aqueous phase.

Accordingly, the objection is obviated. Reconsideration and withdrawal of the objection are respectfully requested.

In view of the foregoing amendment and remarks, allowance of claims 15, 16 and 19-23 is respectfully requested.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Customer No.: 27777
JOHNSON & JOHNSON
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-3385
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YR/YMD
Epm

Respectfully submitted,

By: /Yunling Ren/
Yunling REN
Reg. No. 47,019
Attorney for Applicants